

## Summary of Safety and Effectiveness

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**Submitter's  
Name/Contact  
Person**

The submitter of this special 510(k) is:

Cordis Neurovascular, Inc.  
14000 N.W. 57<sup>th</sup> Court  
Miami Lakes, Florida 33014

Establishment Registration No. 1058196

Contact: Maritza Celaya  
Sr. Regulatory Affairs Associate

Tel: (786) 313-6546

Fax: (786) 313-6480

March 1, 2002

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**Trade Name /  
Common Name**

Trade Name: PROWLER<sup>®</sup> SELECT<sup>™</sup> 10 and 14 Infusion Catheters with and without pre-shaped tips

Common/Classification Name: Catheters, Continuous Flush

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**Classification**

Class II

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**Performance  
Standards**

The FDA under section 514 of the Food, Drug and Cosmetic Act has not established performance standards.

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**Intended Use and  
Device  
Description**

The PROWLER<sup>®</sup> SELECT<sup>™</sup> Infusion Catheters with and without pre-shaped tips are intended to be used as a mechanism for the infusion of various diagnostic, embolic, and therapeutic agents into the vascular systems (Neuro, Peripheral, Coronary), for Guidewire Exchange/Support, and for superselective angiography of the peripheral and coronary vasculatures.

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**Device  
Description**

The PROWLER<sup>®</sup> SELECT<sup>™</sup> 10 and 14 Infusion Catheters with and without pre-shaped tips are a single lumen catheter featuring a stiff proximal shaft and a flexible distal section. The catheter's inner diameter accommodates guidewires of .014" and smaller depending on the catheter type. The catheter body is radiopaque with one or two distinguishable marker(s) at the distal tip. It includes a hydrophilic coating on the outside of the shaft as well as a PTFE liner on the inner lumen.

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*Continued on next page*

**Summary of Safety and Effectiveness, Continued** 0-000021

**Predicate Devices** The predicate devices are listed in the table below:

Device	Company	510 (k) Number	Product Code
PROWLER <sup>®</sup> Infusion Catheters	Cordis Neurovascular, Inc.	K965181 K972518	74KRA
PROWLER <sup>®</sup> PLUS Infusion Catheters	Cordis Neurovascular, Inc.	K993266	74KRA
PROWLER <sup>®</sup> Infusion Catheters with pre-shaped tips	Cordis Neurovascular, Inc.	K003925	74KRA

**Summary of  
Studies**

Design verification testing showed that the PROWLER<sup>®</sup> SELECT<sup>™</sup> 10 and 14 Infusion Catheters with and without pre-shaped tips performed as intended. No new questions of safety and effectiveness were raised. Design verification testing included:

- Outer Diameter Dimension Inspection (pre-coating)
- Visual Inspection
- Flexible Coil Length Inspection/Distal Zone Length Inspection
- Lateral Stiffness
- Trackability
- Joint Pull Test
- Static Burst Testing

All materials used in the PROWLER<sup>®</sup> SELECT<sup>™</sup> 10 and 14 Infusion Catheters with and without pre-shaped tips are biocompatible.

**Summary of  
Substantial  
Equivalence**

The PROWLER<sup>®</sup> SELECT<sup>™</sup> 10 and 14 Infusion Catheters with and without pre-shaped tips are substantially equivalent to the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAR 27 2002**

Ms. Maritza Celaya  
Sr. Regulatory Affairs Associate  
Cordis Neurovascular, Inc.  
14000 N.W. 57<sup>th</sup> Court  
Miami Lakes, FL 33014

Re: K020680  
PROWLER® SELECT™ 10 and 14 Infusion Catheters with and without preshaped tips  
Regulation Number: 21 CFR 870.1210  
Regulation Name: Continuous Flush Catheter  
Regulatory Class: Class II (two)  
Product Code: KRA  
Dated: March 1, 2002  
Received: March 4, 2002

Dear Ms. Celaya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

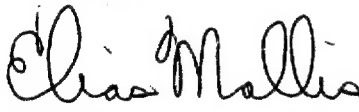
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for

Bram Zuckerman, M.D.  
Acting Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K020680

Device Name: PROWLER® SELECT™ 10 and 14 Infusion Catheters (with and without pre-shapes)

### Indications for Use Statement

The PROWLER® SELECT™ Infusion Catheters are intended to be used as a mechanism for the infusion of various diagnostic, embolic, and therapeutic agents into the vascular systems (Neuro, Peripheral, Coronary), for Guidewire Exchange/Support, and for superselective angiography of the peripheral and coronary vasculatures.

Division of Cardiovascular & Respiratory Devices

510(k) Number Elan M. M. M.  
K020680

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-The-Counter Use ☐